

Remarks and Arguments

Claims 25-31 have been added and claims 4 and 23 have been canceled. It is believed that the new claims do not contain new matter.

A. THE 35 U.S.C. §102 REJECTIONS

1. Claim 1-2, 11 and 23

Claims 1-2, 11 and 23 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No 6290728 issued to Phelps et al. (hereinafter "Phelps").

35 U.S.C. §102(b) states:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

MPEP Section 2131 states in relevant part:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

It is respectfully submitted that Phelps does not anticipate each and every element of amended claim 1 for at least the reason that it does not

teach “[a] stent comprising. . . an end structure . . . including predefined bend locations comprising areas of reduced cross-section as compared to areas of adjacent locations.”

Claims 2 and 11 depend from claim 1, and are therefore novel over Phelps for at least the same reason as claim 1.

2. Claims 1 and 9

Claims 1 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Publication Number 2004/0186555 by Bonsignore et al. (hereinafter “Bonsignore”).

It is respectfully submitted that Bonsignore does not anticipate each and every element of amended claim 1 for at least the reason that it does not teach “[a] stent comprising . . . an end structure . . . including predefined bend locations comprising areas of reduced cross-section as compared to areas of adjacent locations.” Claim 9 indirectly depends from claim 1, and is also novel over Bonsignore for at least this reason.

B. THE 35 U.S.C. §103 REJECTIONS

Claims 3-8, 10, 12-17 and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over Phelps in view of U.S. Patent No. 6203569 to Wijay (hereinafter “Wijay”). Claims 18-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bonsignore in view of Wijay.

In accordance with MPEP §2143.03, to establish a *prima facie* case of obviousness 1) the prior art reference (or references when combined) must teach or suggest *all* of the claim limitations; 2) there must be some

suggestion or motivation to modify a reference or combine references; and
3) there must be a reasonable expectation of success.

1. The References Do Not Suggest or Teach All Claim Limitations

a. Claims 3-8, 10, 12-17 and 24

The Office alleges that 3-8, 10, 12-17 and 24 are obvious based on Phelps and Wijay, stating that “Phelps does not disclose the use of notches to facilitate bending [but] Wijay teaches the use of notches for the purpose of bending sections of a [stent].”

While Applicants agree with the Office’s statement that Phelps does not disclose the use of notches to facilitate bending, they respectfully submit that Phelps and Wijay do not alone or in combination teach all limitations of amended claim 1 and of the other rejected claims that depend on claim 1. In particular, neither Phelps nor Wijay are believed to teach “an end structure adapted to be flared... and the end structure including predefined bend locations comprising areas of reduced cross-section as compared to areas of adjacent locations” as required by claim 1. While Wijay teaches notches, he does not teach stents with end structures and thus cannot logically teach a flaring end structures with areas of reduced cross section. Each of claims 3-8, 10 and 12-17 depend from claim 1, and hence are novel and nonobvious over this art for at least this reason.

Similarly Phelps and Wijay do not together disclose all the claim limitations of claim 3 at least for the reason that claim 3 requires “wherein each predefined bend location includes one or more notches” and claim 1, from which claim 3 depends requires that the “end structure includ[es]

predefined bend locations”. As the Examiner states, Phelps does not disclose notches. Wijay does not disclose notches on a flaring end structure of a stent. (see e.g., Figure 1).

With reference to claim 5, the Examiner has not pointed to any teaching in Wijay that clearly disclose a particular amount by which the areas of reduced cross-section are smaller than adjacent locations.

Applicants respectfully disagree with the Examiner’s assertion that Wijay teaches “linking members” as claimed in claim 12. Claim 12 requires “linking members that extend between *the end struts*” (emphasis added), and claim 11, from which claim 12 depends, requires that “the end structure includes a plurality of end struts having base ends connected to the main body”. Wijay does not disclose stents with an end structure and hence cannot logically teach the above limitation. Thus, Phelps and Wijay do not together or alone teach each of the limitations of claim 12.

Similarly, since Wijay does not teach “linking members” or “end struts” of claim 12, it similarly does not teach them as required in claim 13 which depends from claim 12.

Referring now to claim 14, the Examiner has not pointed to any sections of Phelps or Wijay that teach “regions of reduced radial wall thickness for facilitating flaring of the end struts”. In particular, the Examiner has not pointed to any sections of Wijay that teach stents with end sections having regions of reduced radial wall thickness.

Thus, the Office has not met the *prima facie* case for claims 15-17, which depend from claim 14, for at least the same reasons as for claim 14.

With reference to claim 24, the Office has again not met its prima facie case. In particular, the Office has not pointed to any teaching of “end struts being thinned along their lengths relative to the main body for facilitating flaring the end struts” as required by claim 24. In particular, the Office has not pointed to any teaching in Wijay or Phelps of end struts that are thinned out, or end struts being thinned along their lengths relative to the main body for facilitating flaring of the end struts. While Wijay teaches notches, it does not teach end struts, flared end struts, or end struts thinned out along their length.

b. Claims 18-22

The Office rejected claims 18-22 on the basis that Bonsignore “discloses a stent with support members . . . Wijay teaches the use of notches for the purpose of bending sections of a stent”. The Office further states “that examiner is considering enlargement 802 to be an end strut connected to the main body.”

Applicants respectfully disagree with the Examiner’s conclusion that each limitation of claims 18-22 are taught by Bonsignore and Wijay and in particular that Bonsignore’s marker inserts 802 are end struts.

Bonsignore states in paragraph 65 of the application as published:

FIG. 8 is a cross-sectional view of a marker housing 802. The housing 802 may be elliptical when observed from the outer surface as illustrated in FIG. 7. As a result of the laser cutting process, the hole 806 in the marker housing 802 is conical in the radial direction with the outer surface 808 having a diameter larger than the diameter of the inner surface 810, as illustrated in FIG. 8. The conical tapering in the marker housing 802 is beneficial in

providing an interference fit between the marker insert 804 and the marker housing 802 to prevent the marker insert 804 from being dislodged once the stent 100 is deployed.

The Patent Office has not pointed to any portion of Bonsignore that teaches that marker inserts 802 are “end struts adapted to be flared relative to the main body” as required by claim 18. For at least this reason, it is respectfully submitted that Bonsignore and Wijay do not together teach or suggest every claim limitation of claim 18, or the claims that depend from claim 18.

2. The Art Teaches Away From The Claimed Invention

MPEP 2143.01 states in relevant part:

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.) . . . In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Applicants respectfully submit that the art teaches away from the claimed invention for the following reason. The Office states that it would have been obvious to combine Wijay with Phelps or

Bonsignore to obtain the invention as claimed in various claims. On page 2, lines 28-29 of the application as filed, the specification states:

One embodiment of the present disclosure relates to a stent having predefined bend locations that facilitate flaring the end of the stent.

It is respectfully submitted that Wigay teaches away from this invention. Significantly, Wijay states in col. 7, lines 27-35 (emphasis added):

By use of the cross-sectional area changes, the applied stresses from radial expansion are focused to this transition zone as opposed to other places, such as the return bends. By focusing the deformation to the transition zone, stress is minimized or reduced in the reverse bend section, such as 12 or 14, and further the tendency of the reverse bends such as 12 or 14 to protrude out of the cylindrical surface defined by the stent S is greatly reduced, if not eliminated.

Thus, Wijay teaches cross-sectional changes for the purpose of *greatly reducing or eliminating* protrusion from the cylindrical surface of reverse bend sections of the stent, rather than facilitating flaring.

Wijay teaches away from the invention of each of the independent claims. Claims 1, 28 and 30 require stents comprising “areas of reduced cross-section . . . for *facilitating flaring of the end struts*” (emphasis added). Wijay further teaches away from “regions of reduced radial wall thickness *for facilitating flaring of the end struts*” (independent claim 14; emphasis added). Independent claim 18 includes a limitation directed to stents with “end struts defining *notches for facilitating flaring of the end structure*” (emphasis added), which again is opposite to Wijay’s teaching. Similarly,

Wijay teaches away from the invention of independent claim 24 which requires “end struts being thinned along their lengths . . . *for facilitating flaring of the end struts*” (emphasis added).

Thus, it is respectfully that the Office has not met the requirements of the prima facie case for each of the independent claims, nor for any claims that depend therefrom because the art teaches away from the claimed invention(s).

3. Improper Combination of References (Change Principle Operation of Reference)

Applicant(s) respectfully traverse(s) the rejection of claims 3-8, 10, 12-17, 24 based on Phelps in view of Wijay on the grounds that Phelps and Wijay are not properly combinable. First, there is no teaching, disclosure, suggestion that the apparatus taught in Phelps should be modified to include all or part of the teachings of Wijay or that their respective teachings be combined. The combination is improper because the proposed modification of Wijay would change the principle of operation of Phelps, such combination being prohibited by MPEP 2143.01 which specifically recites:

THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a

rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

In setting forth the rejection, the Examiner has stated:

[I]t would have been obvious to one of ordinary skill in the art to modify the bend locations of Phelps to include notches, shoulders and linking members as taught by Wijay for the purpose of facilitating improved bending and reducing strain at the bend location.

Applicant(s) respectfully disagree(s) with the Examiner's remarks. As stated above, Wijay states in col. 7, lines 27-35:

By use of the cross-sectional area changes, the applied stresses from radial expansion are focused to this transition zone as opposed to other places, such as the return bends. By focusing the deformation to the transition zone, stress is minimized or reduced in the reverse bend section, such as 12 or 14, and further the tendency of the reverse bends such as 12 or 14 to protrude out of the cylindrical surface defined by the stent S is greatly reduced, if not eliminated.

Thus, Wijay expressly teaches that stress is increased at the bend locations, and protrusion of adjacent reverse bends out of the cylindrical surface is greatly reduced, if not eliminated. It is respectfully submitted that Wijay teaches away from flared end(s) of a stent, and thus is not properly combinable with Phelps which teaches a stent with flared ends.

Further claims 18-22 were rejected over Bonsignore in view of Wijay. Bonsignore appears to show a flared stent (see Fig. 3). It is respectfully submitted that it would be improper to combine the teachings of Wijay with Bonsignore for reasons analogous to those discussed above in reference to the improper combination of Wijay and Phelps.

C. NEW CLAIMS

It is respectfully submitted that the newly added claims are novel and non-obvious for reasons that would be understood in view of the arguments presented herein.

RECONSIDERATION

It is believed that all claims of the present application are now in condition for allowance.

Reconsideration of this application is respectfully requested. If the Examiner believes that a teleconference would expedite prosecution of the present application the Examiner is invited to call the Applicant's undersigned attorney at the Examiner's earliest convenience.

Any amendments or cancellation or submissions with respect to the claims herein is made without prejudice and is not an admission that said canceled or amended or otherwise affected subject matter is not patentable. Applicant reserves the right to pursue canceled or amended subject matter in one or more continuation, divisional or continuation-in-part applications.

Respectfully submitted

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Date: 2007-08-08

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